K061595

Special 510k Submission
Xaminer Digital Radiographic Detector

510 k Summary

AUG 17 2006

Submitter: Imaging Dynamics Company Ltd
Suite 121, 2340 Pegasus way NE
Calgary, AB
Canada T2E 8M5

Contact Person: Shirantha Samarappuli – Manager – Regulatory Affairs
Tel: 403 251 9939, Fax: 403 251 1771

Date Prepared: Jun 01, 2006

Device Name: Xaminer Digital Radiographic x-ray detector

Marketed Device: Xplorer 1000 Digital Radiographic x-ray detector

Device Description:

The Xaminer is the latest version of Xplorer digital radiographic detectors. It includes features and functions that have been developed since the introduction of the original Xplorer 1000 (predicate device). Xaminer provides high resolution radiographic images at 3.2 lp/mm in a digital format without use of film, chemistry, cassettes or expensive imaging plates. With 98 % of fill factor in each pixel, there is a maximum efficiency and lower dose required for image capture. It has single CCD detector with 9 mega pixel digitized at 14 bits per pixels

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Shirantha Samarappuli
Manager-Regulatory Affairs
Imaging Dynamics Company Ltd.
Suite 151, 2340 Pegasus Way NE
CALGARY ALBERTA T2E 8M5
CANADA

AUG 20 2013

Re: K061595
Trade/Device Name: Xaminer
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR and MQB
Dated: July 21, 2006
Received: July 24, 2006

Dear Mr. Samarappuli:

This letter corrects our substantially equivalent letter of August 17, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Special 510k Submission
Xaminer Digital Radiographic Detector

Intended Use:

The Xaminer (510k submission device) is integrated into the user's stationary radiography system. This typical configuration permits a qualified/trained doctor or technologist to take a range of head-to-toe diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts on both adult and pediatric patients. Applications can be performed with patient sitting, standing or lying in the prone or supine positions in an integrated system.

The Xaminer (510k submission device) is not intended for mammography.

These intended uses are identical to the Xplorer 1000 (predicate device).

PRESCRIPTION USE ✓ AND/OR OVER-THE-COUNTER _____
(21 CFR 801 SUBPART D) (21 CFR 801 SUBPART C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

(DIVISION SIGN-OFF

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061595